FORM 5. Petition for Review or Notice of Appeal of an Order or Decision of an Agency, Board, or Commission.

United States Court of Appeals for the Federal Circuit

Judith Aronhime, Ramy Lidor-Hadas, Valerie Niddam, Revital Lifshitz and Guy Sambursky, Petitioner or Appellant,

v.

Stephen Robert Byrn, David Andrew Coates, Karen Sue Gushurst, Joseph Francis Krzyzaniak, Zheng Jane Li, Henry Grant Morrison II, Aeri Park and Petinka Ivanova Vlahova, Respondent or Appellee.

PETITION FOR REVIEW

Judith Aronhime, Ramy Lidor-Hadas, Valerie Niddam, Revital Lifshitz and Guy Sambursky (name all parties* bringing the petition or appeal) hereby petition/appeal the court for review of the Decision in Interference No. 105,384 (describe the order or decision and include decision number) of the Board of Patents and Appeals and Interferences (name the agency, board, or officer) entered on August 15 2007, _____ (date). The order or decision was received on August 15 2007, _____ (date).

_____
(Signature of petitioner, appellant or attorney)

_____
(Address and phone number of petitioner, appellant or attorney

Steven J. Lee
Kenyon & Kenyon
One Broadway
New York, NY 10004
Tel.: 212-452-7000

Reset Fields

*See Fed. R. App. P. 15 for permissible ways of identifying petitioners.

Form 8

FORM 8. Entry of Appearance

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Judith Aronhime, Ramy Lidor-Hadas, Valerie Niddam, Revital Lifshitz and Guy Sambursky

v. Stephen Robert Byrn, David Andrew Coates, Karen Sue Gushurst, Joseph Francis Krzyzaniak, Zheng Jane Li, Henry Grant Morrison II, Aeri Park and Petinka Ivanova Vlahova

No. _____

ENTRY OF APPEARANCE

(INSTRUCTIONS: Counsel should refer to Fed. Cir. R. 47.3. Pro se petitioners and appellants should read paragraphs 1 and 18 of the Guide for Pro Se Petitioners and Appellants. File this form with the clerk and serve a copy of it on the principal attorney for each party.)

Please enter my appearance (select one):

☐ Pro Se ☑ As counsel for: Judith Aronhime, Ramy Lidor-Hadas, Valerie Niddam, Revital Lifshitz and Guy Sambursky

Name of party

I am, or the party I represent is (select one):

☐ Petitioner ☐ Respondent ☐ Amicus curiae ☐ Cross Appellant

☑ Appellant ☐ Appellee ☐ Intervenor

As amicus curiae or intervenor, this party supports (select one):

☐ Petitioner or appellant ☐ Respondent or appellee

My address and telephone are:

Name:	Steven J. Lee
Law firm:	Kenyon & Kenyon LLP
Address:	1 Broadway
City, State and ZIP:	New York, N.Y. 10004
Telephone:	212-425-7200
Fax #:	212-425-5288
E-mail address:	slee@kenyon.com

Statement to be completed by counsel only (select one):

☑ I am the principal attorney for this party in this case and will accept all service for the party. I agree to inform all other counsel in this case of the matters served upon me.

☐ I am replacing _____ as the principal attorney who will/will not remain on the case. [Government attorneys only.]

☐ I am not the principal attorney for this party in this case.

Date admitted to Federal Circuit bar (counsel only): _____

This is my first appearance before the United States Court of Appeals for the Federal Circuit (counsel only):

☐ Yes ☑ No

☐ A courtroom accessible to the handicapped is required if oral argument is scheduled.

10/12/07
Date

Signature of pro se or counsel

cc:

Reset Fields

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Judith Aronhime, Ramy Lidor-Hadas, Valerie Niddam, Revital Lifshitz and Guy Sambursky

v.

Stephen Robert Byrn, David Andrew Coates, Karen Sue Gushurst, Joseph Francis Krzyzaniak, Zheng Jane Li, Henry Grant Morrison II, Aeri Park and Petinka Ivanova Vlahova

No. _____

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)

Steven J. Lee certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Judith Aronhime, Ramy Lidor-Hadas, Valerie Niddam, Revital Lifshitz and Guy Sambursky

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Teva Pharmaceuticals Industries, Ltd.
5 Basel Street
P.O. Box 3190
Petach Tiqva, Isreal 49131

Teva Pharmaceuticals USA, Inc.
P.O. Box 1090
1090 Horsham Road
North Whales, Pennsylvania 19454

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

4. ☑ There is no such corporation as listed in paragraph 3.

5. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Steven J. Lee, John F. Resek
Kenyon & Kenyon LLP
One Broadway
New York, N.Y. 10004

10/12/07
Date

Signature of counsel

Steven J. Lee
Printed name of counsel

Reset Fields

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the PETITION FOR REVIEW, CERTIFICATE OF INTEREST, ENTRY OF APPEARANCE, FEDERAL CIRCUIT APPEAL INFORMATION SHEET, MEMORANDUM OPINION and ORDER, and JUDGMENT were caused to be served on the following by Express Mail (U.S. Postal Service) on this 12th day of October, 2007, envelopes addressed to:

Clerk of the Court
US District Court of Appeals for the Federal Circuit
717 Madison Place, NW
Washington, DC 20439

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United States Patent and Trademark Office
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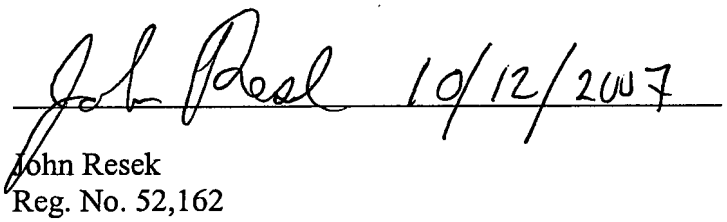

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FORM 7. Appeal Information Sheet

FEDERAL CIRCUIT APPEAL INFORMATION SHEET

☐ United States District Court for the _____

☐ United States Court of International Trade

☐ United States Court of Federal Claims

☐ United States Court of Appeals for Veterans Claims

Type of case: Appeal of a Decision by the Board of Patent Appeals and Interferences

Judith Aronhime, Ramy Lidor-Hadas, Valerie Niddam, Revital Lifshitz and Guy Sambursky v. Stephen Robert Byrn, David Andrew Coates, Karen Sue Gushurst, Joseph Francis Krzyzaniak, Zheng Jane Li, Henry Grant Morrison II, Aeri Park and Petinka Ivanova Vlahova

(List all parties. Use an asterisk to indicate dismissed or withdrawn parties. Use a separate sheet if needed. Explain any discrepancy with the caption used on the judgment, order, or opinion.)

Docket No. U.S. Interference No. 105, 384 Date of Judgment or Order August 15, 2007

Cross or related appeal? _____ Date of Notice of Appeal October 12, 2007

Appellant is: ☐ Plaintiff ☐ Defendant ☑ Other (explain) Junior Party

FEES: Court of Appeals docket fee paid? ☑ Yes ☐ No

U.S. Appeal? ☐ Yes ☐ No

In forma pauperis? ☐ Yes ☐ No

Is this matter under seal? ☐ Yes ☐ No

COUNSEL: (List name, firm, address, and telephone of lead counsel for each party. Indicate party represented. Use separate sheet if needed.)

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COURT REPORTER: (Name and telephone): _____

IMPORTANT: Attach a copy of the judgment or order appealed from and any supporting opinion or memorandum. Forward together with a copy of the notice of appeal and certified docket entries.

Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, NW
Washington, DC 20439

Reset Fields

BoxInterferences@uspto.gov
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Paper 89
Entered: 15 August 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

STEPHEN ROBERT **BYRN**, DAVID ANDREW COATES,
KAREN SUE GUSHURST, JOSEPH FRANCIS KRZYZANIAK,
ZHENG JANE LI, HENRY GRANT MORRISON II,
AERI PARK and PETRINKA IVANOVA VLAHOVA,

Junior Party
Patent 6,605,729 B1,

v.

JUDITH **ARONHIME**, RAMY LIDOR-HADA, VALERIE NIDDAM,
RETITAL LIFSHIRTZ and GUY SHAMBURSKY,

Senior Party
Application 09/997,126.

Patent Interference 105,384 McK
Technology Center 1600

Before: FRED E. McKELVEY, *Senior Administrative Patent Judge*, and SALLY GARDNER LANE and JAMES T. MOORE, *Administrative Patent Judges*.

McKELVEY, *Senior Administrative Patent Judge*.

JUDGMENT

Upon consideration of the record, it is

ORDERDED that judgment on priority as to Count 2 (the sole count in the interference; Paper 64, pages 4-5) is awarded against Senior Party JUDITH ARONHIME, RAMY LIDOR-HADA, VALERIE NIDDAM,

RETITAL LIFSHIRTZ and GUY SHAMBURSKY.

FURTHER ORDERED that Senior Party JUDITH ARONHIME, RAMY LIDOR-HADA, VALERIE NIDDAM, RETITAL LIFSHIRTZ and GUY SHAMBURSKY is not entitled to a patent containing claims 147-166 (which have been designated as corresponding to Count 2) of:

application 09/997,126
filed 29 November 2001.

FURTHER ORDERED that if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c).

FURTHER ORDERED that a copy of this JUDGMENT shall be placed in the files of (1) Byrn U.S. Patent 6,605,729 B1 and (2) Aronhime application 09/997,126.

/ss/ Fred E. McKelvey
FRED E. McKELVEY
Senior Administrative Patent Judge

/ss/ Sally Gardner Lane
SALLY GARDNER LANE
Administrative Patent Judge

/ss/ James T. Moore
JAMES T. MOORE
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

cc (via Electronic Mail)

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Paper 88
Entered: 15 August 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

STEPHEN ROBERT **BYRN**, DAVID ANDREW COATES,
KAREN SUE GUSHURST, JOSEPH FRANCIS KRZYZANIAK,
ZHENG JANE LI, HENRY GRANT MORRISON II,
AERI PARK and PETRINKA IVANOVA VLAHOVA,

Junior Party
Patent 6,605,729 B1,

v.

JUDITH **ARONHIME**, RAMY LIDOR-HADA, VALERIE NIDDAM,
RETITAL LIFSHIRTZ and GUY SHAMBURSKY,

Senior Party
Application 09/997,126.

Patent Interference 105,384 McK
Technology Center 1600

Before: FRED E. McKELVEY, *Senior Administrative Patent Judge*, and SALLY GARDNER LANE and JAMES T. MOORE, *Administrative Patent Judges*.

McKELVEY, *Senior Administrative Patent Judge*.

MEMORANDUM OPINION and ORDER

A. Introduction

Bryn motion 3

Byrn Motion 3 seeks entry of a judgment based on priority of invention. Paper 70.

A copy of the docket entries identifying numbers of papers filed in the interference is attached as Appendix 1.

Aronhime timely filed Aronhime Opposition 3. Paper 74.

Byrn timely filed Byrn Reply 3. Paper 75.

Byrn Motion 3 is *granted.*

Aronhime combined motions 2-5

Aronhime Combined Motions 2-5 seeks entry of judgment against Byrn claim 6 (the only Byrn patent claim involved in the interference) based on an alleged failure to comply with the enablement and written description requirements of the first paragraph of 35 U.S.C. § 112. Paper 71.

Byrn timely filed Byrn Opposition 2-5. Paper 69.

Aronhime timely filed Aronhime Combined Reply 2-5. Paper 72.

Aronhime combined motions 2-5 is *denied.*

Aronhime miscellaneous motion 7

Aronhime Miscellaneous Motion 7 seeks to exclude from evidence (1) all or a part of Byrn Exhibit 2116 and (2) all of Byrn Exhibit 2117. Paper 77.

Byrn timely filed Byrn opposition 7. Paper 81.

Aronhime timely filed Aronhime reply 7. Paper 82.

Aronhime Miscellaneous Motion 7 is *denied-in-part and dismissed-in-part.*

Oral argument

Oral argument on motions took place on 01 August 2007.

Oral argument was transcribed.

B. Findings of Fact

The Interference

The interference involves junior party Byrn versus senior party Aronhime.

Byrn is involved on the basis of U.S. Patent 6,605,729 B1, issued 12 August 2003, based on application 10/184,669, filed 28 June 2002. Ex. 2001.

Byrn has been accorded a constructive reduction to practice, *i.e.*, benefit for the purpose of priority, of provisional application 60/302,049, filed **29 June 2001**. Ex. 2001, page 1.

Warner-Lambert Company LLC, which is owned by Pfizer, Inc., is the real party in interest for Byrn. Paper 5.

Aronhime is involved on the basis of application 09/997,126, filed 29 November 2001. Ex. 1008.

Aronhime has been accorded a constructive reduction to practice, *i.e.*, benefit for the purpose of priority, of provisional application 60/267,897, filed **09 February 2001**. Paper 1, page 4.

Teva Pharmaceuticals Industries, Inc., is the real party in interest for Aronhime. Paper 11.

Byrn is junior party because its earliest constructive reduction to practice of 29 June 2001 is later than the constructive reduction to practice accorded to Aronhime of 09 February 2001.

The Count and Claims Corresponding to the Count

The interference involves one count, which is Count 2. *See* Paper 65, pages 4-5 (Decision granting Byrn Motion 2 entered 20 September 2006) and Paper 66, pages 2-3 (Redeclaration, entered 20 September 2006).

Count 2, which was substituted for original Count 1 (Paper 1, page 6), reads [matter in brackets added; matter in bold shows what was added to Count 2 which does not appear in original Count 1]:

> A crystalline [Aronhime] Form VIII atorvastatin hemi-calcium and solvates thereof characterized by a powder X-ray diffraction pattern generated using CuK_α radiation with peaks at:
>
> 4.8
> 5.2
> 8.0
> 9.2
> 9.6
> 19.0
> 20.0
> 24.0 and
> 29.0
>
> ± 0.2 degrees two-theta
>
> or
>
> a crystalline [Byrn] Form X atorvastatin or a hydrate thereof having an X-ray power diffraction containing the following 2Θ values measured using CuK_α radiation:
>
> 4.7
> 5.2
> 5.8
> 6.9
> 7.9
> 9.2

9.5
10.3 (broad)
11.8
16.1
16.9
19.1
19.8
21.4
22.3 (broad)
23.7 (broad)
24.4 and
28.7

± 0.2 degrees two-theta.

Count 2 is essentially an alternative statement of (1) Markush member a) of Aronhime claim 147 (Ex. 2003, first page, but numbered page 2) [the Aronhime alternative of Count 2] and (2) Byrn claim 6 (Ex. 2001, col. 29) [the Byrn alternative of Count 2].

The Byrn patent contains claims 1-15, but only Byrn claim 6 has been designated as corresponding to Count 2.

The Aronhime application contains claims 147-166, all of which have been designated as corresponding to Count 2.

The Byrn Invention

Some of the description of the Byrn invention is taken from our Memorandum Opinion and Order denying Byrn Motion 1. Paper 63.

The Byrn invention is described as relating to "novel crystalline forms of atorvastatin." Ex. 2001, col. 1:12-13.

According to Byrn, atorvastatin in the form of its calcium salt has been marketed as Lipitor®. Ex. 2001, col. 1:33-45. *See also* Ex. 1008, page 2:19-20.

Atorvastatin calcium is said to be useful for treating humans suffering from hyperlipidemia, hypercholesterolemia, osteoporosis and Alzheimer's disease. Ex. 2001, col. 1:21-23 and 33-54.

While the Byrn patent describes numerous crystalline forms of atorvastatin, the embodiment relevant to the interference is what Byrn identifies as "a sixth aspect" of the invention, which is Byrn Form X. Ex. 2001, col. 8:36 to col. 10:02.

Other Byrn forms are described in the Byrn patent, but are not involved in the interference.

Byrn's use of the Roman number "X" to identify one of Byrn's crystalline forms is arbitrary.

In other words, other inventors may use a different numeral to identify the same or different crystalline forms. *See* Ex. 1054, page 7, ¶ 15 for a discussion by an Aronhime witness of why Roman numbers are different for different inventors or companies.

Aronhime uses Aronhime Form VIII to define what Aronhime believes, and the Board has found, is the same patentable invention as Byrn Form X.

The Byrn atorvastatin is described as being prepared as a calcium salt. Col. 2:28.

Byrn Form X contains about 3 mol of water, preferably 3 mol of water. Col. 23:21-24.

According to Byrn, crystalline forms of atorvastatin having equivalent forms of X-ray powder diffractograms fall within the scope of the Byrn invention. Col. 23:30-33.

Three methods for making Byrn Form X are described by Byrn. Ex. 2001, col. 27:55 through col. 28:04.

Method A: "A slurry of amorphous atorvastatin calcium (U.S. Pat. No. 5,273,995) in isopropanol/water (9:1) was stirred for a few days, filtered, and air dried to afford crystalline Form X atorvastatin." Ex. 2001, col. 27:55-59.

Method B: "A slurry of amorphous atorvastatin calcium (U.S. Pat. No. 5,273,995)) in isopropanol/water (9:1) was stirred for 5 days, filtered and air dried to afford crystalline Form X atorvastatin." Ex. 2001, col. 27:60-64.

The difference between Method A and Method B seems to be that in Method B stirring is said to have occurred for 5 days whereas in Method A stirring is said to have occurred for a "few" days.

Method C: "A saturated solution of amorphous atorvastatin calcium (U.S. Pat. No. 5,273,995) in isopropanol/water (9:1) was stirred for 2 days, filtered and air dried to afford crystalline Form X atorvastatin." Ex. 2001, col. 27:65 to col. 28:02.

Aronhime conducted experiments to reproduce Byrn Methods A, B, and C. The water content reported by Aronhime for the products made using each of Methods A, B, and C are as follows:

Method A 1.88%

Method B 0.89%

Method C 2.03%

See Byrn combined opposition 2-5, statement of facts, ¶¶ 52-55 and Aronhime combined reply 2-5, statement of facts, ¶¶ 52-55. *See also* Ex. 1011 ¶ 91 (Testimony of Dr. Rogers, a witness for Aronhime).

According to the Byrn patent, Method C produces a crystalline Form X which is characterized as a "trihydrate" having "3.5 mol of water". Col. 28:3-4. The parties are not in agreement on this fact. *Compare* (1)

Byrn combined opposition 2-5, statement of facts, ¶ 50 with (2) Aronhime combined reply 2-5, statement of facts, ¶ 50. While we are inclined to think that Byrn has the better view given the location in the patent of the language at col. 28:3-4, at the end of the day it does not matter whether Byrn intended the 3.5 mol to apply only to Method C or to all of Methods A, B, and C.

Byrn Form X is said to be advantageous in that it can be prepared from what Byrn characterizes as a less toxic isopropanol-water system. Ex. 1008, col. 24:27-29.

According to Byrn, 19 crystalline forms of atorvastatin are known. Ex. 2001, col. 19:24.

Each crystalline form of atorvastatin is different.

Thus, while the empirical chemical formula of all forms may be the same, the crystalline structure of each form is different. Ex 2001, col. 23:41-44: "One cannot ascertain any particular crystalline form from the chemical formula nor does the chemical formula tell one how to identify any particular crystalline solid form or describe its properties."

According to Byrn, and we do not understand Aronhime to disagree, one way to identify a particular form of atorvastatin is by diffraction, in particular generation of a diffractogram through the use of an X-ray powder diffractometer.

A diffractogram for Byrn Form X is said to have been obtained from a Shimadzu XRD-6000 X-ray diffractometer. Ex. 2001, col. 16:35-38. *See also* Byrn Fig. 6. Ex. 2001, col. 15:27-28.

In simple terms, a diffractometer is used by directing X-rays into a sample at an angle, generally defined as angle theta (Θ). *See* the illustration at the bottom of page 1 of Ex. 2004.

The X-rays will leave the sample at the same angle Θ, thus the term of art 2Θ or two theta (meaning two times Θ).

The X-rays leaving the sample have a given intensity for any particular angle Θ and that intensity can be measured in counts per second.

The intensities show up as peaks on what looks like a graph on a diffractogram.

A diffractogram of Byrn Form X (taken from Byrn Fig. 6) is shown on page 11 of this opinion.

Fig. 6 show that Byrn Form X has peaks along the x-axis (2Θ or two theta axis) at about 19.0 (meaning that Θ was 9.5°) that correspond to an intensity (counts per second) of about 2,600 on the y-axis.

In the Bryn patent, values for 2Θ degrees have been rounded to one decimal place. Ex. 2001, col. 18:25-26.

The intensities for a given sample vary as a function of angle Θ. As can be seen from the diffractogram for Byrn Form X, the intensity varies depending on the value of 2Θ.

At one angle Θ the intensity can be significant and at other angles it may be minimal.

The peaks obtained from one crystalline form of atorvastatin will be different from the peaks obtained from a different crystalline form of atorvastatin.

In Table 1 of Byrn, relative intensities of >10% are reported. Ex. 2001, col. 18:23-25.

A diffractometer is not a "perfect" instrument in the sense that its results can be subject to errors. Ex. 2001, col. 17:17 through col. 18:22.

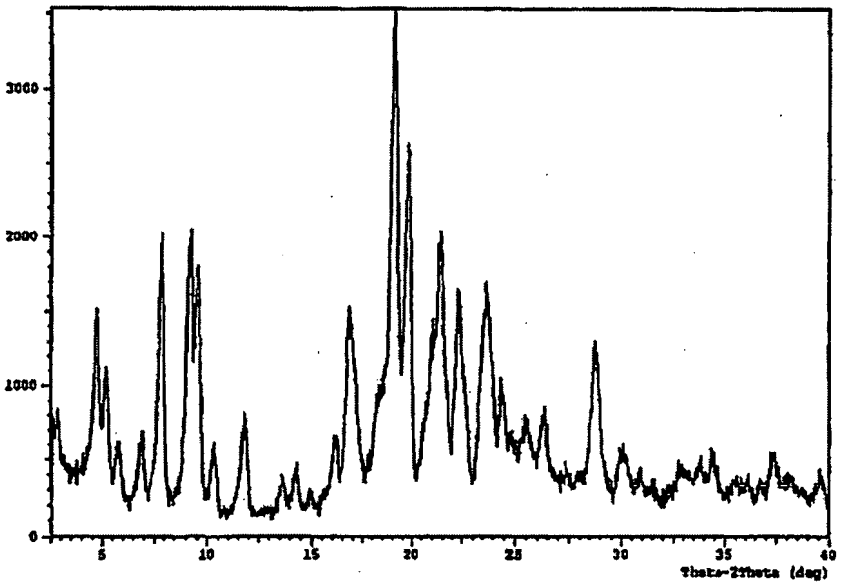
According to Byrn, errors can occur, *inter alia*, due to (a) sample preparation errors, (b) instrument errors, (c) calibration errors, (d) operator

errors, and (e) what Byrn calls "preferred orientation." Ex. 2001, col. 17:17-23.

Diffractogram—Byrn Form XI

A diffractograms of Byrn Form X is shown on the next page:

Figure 6



Form X

The figure shows a diffractogram of Byrn Form X

Disagreement on scope of Byrn claim 6

The parties do not agree on the scope of claim 6 (which is the Byrn alternative of Count 2).

According to Aronhime, if claim 6 is given a broad interpretation, then claim 6 is not patentable due to an alleged lack of enablement and written description. Paper 74, page 2.

On the other hand, if claim 6 is given a narrow interpretation, then Byrn has not shown priority vis-à-vis Aronhime in Byrn motion 3. *Id.*

If claim 6 is given a broad construction, Aronhime maintains that there are three separate enablement and written description problems with Byrn claim 6.

First, claim 6 is said to be too broad and lacks a written description because it is not limited to a Form X which contains both isopropanol and water. *See e.g.*, Paper 74, page 4 *et seq*. Methods A, B, and C all describe the use of isopropanol as a solvent in which the Form X crystalline material is made.

Second, claiming the "art" to be unpredictable, claim 6 is further said to be too broad because it is not limited to a trihydrate and the Byrn specification is said to lack an enabling description of how to make anything other than a trihydrate. *See, e.g.*, Paper 74, page 5 *et seq*.

Third, claim 6 is said to be too broad because it encompasses salts other than a calcium salt and the Byrn specification is said to lack an enabling description of how to makes atorvastatin salts other than calcium salts. *See, e.g.*, Paper 74, page 7 *et seq*.

Byrn disagrees with Aronhime and maintains that Byrn claim 6 should be interpreted to cover (1) atorvastatin calcium or a hydrate thereof (2)

having X-ray powder diffraction containing the following 2Θ values measured using CuK_α radiation:

4.7
5.2
5.8
6.9
7.9
9.2
9.5
10.3 (broad)
11.8
16.1
16.9
19.1
19.8
21.4
22.3 (broad)
23.7 (broad)
24.4 and
28.7

Responding to Aronhime's three points, Byrn makes the following points.

First, Byrn claim 6 does not recite a solvate or the use of any particular solvent to make Form X. *See, e.g.*, Paper 69, page 4 *et seq*.

Second, Aronhime has not established that Form X can exist only as a trihydrate, noting that the Byrn specification states that Form X has "about 3 mole water." *See e.g.*, Paper 69, page 7 *et seq*.

Third, with respect to the "salt" issue, Byrn maintains that a properly construed claim 6 is limited to Form X atorvastatin calcium salts. *See, e.g.*, Paper 69, page 8 *et seq*.

Other findings appear below.

C. Resolution of scope of Byrn claim 6

A claim in an application or a patent involved in an interference is given its broadest reasonable construction in light of the specification of the application or patent in which it appears. 37 C.F.R. § 41.200(b) (2006).

The reason for the rule is that both an applicant and a patentee may amend claims to meet patentability objections by an opponent. The applicant moves to add or substitute a claim for a claim under attack. A patentee files a reissue application to add a claim to its patent.

In this case, despite Aronhime's attack, Byrn did not seek to file a reissue.

Byrn claim 6 reads:

> a crystalline Form X atorvastatin or a hydrate thereof having an X-ray power diffraction containing the following 2Θ values measured using CuK_α radiation:
>
> 4.7
> 5.2
> 5.8
> 6.9
> 7.9
> 9.2
> 9.5
> 10.3 (broad)
> 11.8
> 16.1
> 16.9
> 19.1
> 19.8
> 21.4
> 22.3 (broad)
> 23.7 (broad)
> 24.4 and
> 28.7

Byrn claim 6 is not a product-by-process claim and therefore does not recite how the crystalline Form X atorvastatin is made. Accordingly, that isopropanol can be used to make Byrn's crystalline Form X atorvastatin is not particularly relevant to determining the scope of the claim. In the words of the statute, the claim covers a composition of matter and there is no statutory *requirement* that a claim to a composition of matter recite in the claim the method by which the composition of matter is made.

In construing a claim and where at all possible, we make every attempt to give a meaning to every word in the claim—a meaning which would be given by one having ordinary skill in the art based upon the underlying specification. *See Merck & Co., Inc. v. Teva Pharmaceuticals USA*, 395 F.3d 1364, 1372, 73 USPQ2d 1641, 1648 (Fed. Cir. 2005) (a claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so).

One point of contention between the parties is whether Byrn claim 6 is limited to a calcium salt.

The language "calcium salt" does not appear in the claim, although it appears in numerous portions of the specification, *e.g.*:

(1) col. 1:16 (hemi-calcium salt) and 34 (atorvastatin calcium);

(2) col. 2:18 (atorvastatin is prepared as its calcium salt);

(3) col. 21:10 (formula showing calcium salt, *e.g.*, Ca^{2+} where 2+ is the valance of calcium); and

(4) col. 27:54 *et seq.* (three methods for making Form X atorvastatin where "amorphous atorvastatin calcium" is used).

There are other portions of the specification which refer to "atorvastatin" without mentioning calcium, *e.g.*:

(1) col. 1:55-67 (referring to patents describing how to make atorvastatin;

(2) col. 8:36-37 (referring to the invention being directed to crystalline Form X atorvastatin and hydrates thereof);

(3) col. 16:35-37 (mentioning that X-ray powder diffraction patterns were generated for Form X atorvastatin on a Shimadzu XRD-6000 X-ray powder diffractometer);

(4) col. 21:15 (mention is made of Form X atorvastatin in relation to chemical shifts, although it should be noted the mention is right under a formula showing a calcium salt);

(5) Form X atorvastatin contains about 3 mol of water; and

(6) col. 28:3-4 (Form X atorvastatin has 3.5 mol of water when measured by Karl Fischer, although it should be noted that the Karl Fischer report comes right after Methods A, B, and C which report use of amorphous atorvastatin calcium).

On balance, we hold that the language "Form X atorvastatin" in Byrn claim 6 has to mean an atorvastatin in calcium form.

While the compound "atorvastatin" *per se* does not have to be a calcium salt, it is reasonably plain to us that the language "Form X" has to be a calcium salt of atorvastatin. There is no convincing description in the specification which would have us conclude that Byrn claim 6, directed to a relatively crystalline form of atorvastatin is anything other than a calcium salt. The only methods described for making "Form X atorvastatin" use "amorphous atorvastatin calcium." The language Form X atorvastatin is used at col. 21 to describe a compound by its formula as a calcium salt.

In duplicating Byrn Methods A, B, and C, using atorvastatin calcium, Aronhime obtained diffractograms which are essentially the same as the diffractogram of Byrn Fig. 6.

Another bone of contention in the case is the meaning of the term "hydrate" in claim 6.

Aronhime says it has to be a tri-hydrate.

Byrn says it just has to be a hydrate.

The plain language of the specification says that Form X atorvastatin will contain about 3 mol of water. Col. 23:22. The language is enough to show that "hydrate" in Byrn claim 3 is not limited to a tri-hydrate.

On this record, we have some additional evidence which is at least marginally relevant to the issue between Byrn and Aronhime. Following a description of Method C for making Form X atorvastatin, Byrn reports a Karl Fischer water content of 3.5 mol of water. Everyone involved in this case knows that Karl Fischer measures all water content, not just water bound in the crystal. *See, e.g.*, (1) Ex. 1078, ¶ 16 (see proposed Aronhime finding 159—Appendix II, Paper 75) and (2) *Silvestri v. Grant*, 496 F.2d 593, 598, 181 USPQ 706, 709 (CCPA 1974) (Karl Fischer cannot distinguish between chemically bound water and water present as an impurity). How much of the 3.5 mol of water is bound in the crystal and how much is not bound we do now know. What we do know, however, is that Aronhime made an attempt to duplicate Methods A, B, and C. According to Aronhime, Methods A, B, and C result in water contents of (A) 1.88%, (B) 0.89% and (C) 2.03%, respectively.

Even assuming *arguendo* that all of the water is bound in the crystal (which is probably not a good assumption), nevertheless none of the Aronhime samples had a water content of 3%. We have no reason to assume

that Aronhime's experiments were not carefully done. While the Aronhime experimental work does not constitute part of the Byrn disclosure, we assume that one skilled in the art reproducing Methods A, B, and C would get Aronhime's results. Stated in other terms, the Aronhime water percentages are "inherently" described by Byrn—at least to the extent that Aronhime argues that the "hydrate" must be a tri-hydrate.

On balance, we hold that the term "hydrate" is not limited to a tri-hydrate.

We will also note that the "Form X atorvastatin" in addition to being a calcium salt must have the 2Θ values set out in the claim.

D. Discussion—Aronhime combined motions 2-5

Aronhime shoots three arrows at Byrn claim 6 hoping at least one will deliver a fatal blow. Unfortunately for Aronhime, all three arrows miss.

Method for making Byrn Form X

The first arrow misses because there is no requirement of law that Byrn set out in its claim how its crystalline Form X atorvastatin is made. All Byrn needed to do, and did, was describe *in the specification* a method for making the new form. It did so in Methods A, B, and C.

According to Aronhime, there is a lack of enablement commensurate in scope with the breadth of the claim because the water:isopropanol mixture is described in the Byrn specification for making Byrn Form X. Aronhime tells us that the Byrn specification would not enable one skilled in the art to make Byrn Form X with other solvents, say methanol. But, we fail to understand why Byrn has failed the enablement and written description requirement when it describes three methods for making Byrn Form X and Aronhime seems to have been able to duplicate those three methods.

Calcium salt

The second arrow misses because Byrn claim 6 is limited to a calcium salt.

Aronhime maintains that the enabling disclosure is not commensurate in scope with the breadth of Byrn claim 6 because Byrn describes only how to make a calcium salt.

We agree that Byrn describes only calcium salts, but as earlier noted we have construed the language "Form X atorvastatin" to be a calcium salt.

Hydrate

The third arrow also misses.

Aronhime maintains that the enabling disclosure is not commensurate in scope with the breadth of Byrn claim 6. Aronhime seemingly agrees that if Byrn claim 6 were limited to a tri-hydrate that all would be well. However, Aronhime says that the word "hydrate" is not limited to a tri-hydrate. Since Byrn teaches only how to make tri-hydrates, Aronhime reasons that the enabling description in the specification is not commensurate in scope with the claim.

As noted earlier, the Byrn specification says that Form X atorvastatin will have about three mol of water. Col. 23:22. By "3 mol of water" Byrn means water of hydration—water bound up as part of the crystalline structure. But, Byrn tells us in the specification that crystal structure can be obtained from X-ray data or approximated from other data. Col. 23:36-37. Byrn claim 6 calls for certain X-ray powder diffraction values. The Byrn specification reveals to one skilled in the art how to make a Form X atorvastatin with those diffraction patterns. The amount of "hydrate", whether it be a tri-hydrate or something else (e.g., the amount of hydrate

present in the Aronhime experiments), is not particularly controlling as long as the product is Form X atorvastatin with the peaks set out in Byrn claim 6.

Disposition of Aronhime combined motions 2-5

Aronhime combined motions 2-5 are *denied.*

E. Findings of fact—priority

We now move to the main event of an interference, priority of invention.

Byrn put on a priority case.

Aronhime did not put on a priority case.

The only issue is whether Byrn has established an actual reduction to practice prior to the constructive reduction to practice date accorded to Aronhime—09 February 2001.

As the transcript of oral argument will reveal, there are two matters which are not issues.

First, there was no need for testing of the compounds made by Byrn—everyone remotely connected with this art would have known that the utility of crystalline atorvastatin would involve administering it in the same manner in which Lipitor is administered.

Second, Aronhime does not contend that Byrn suppressed or concealed the invention. We also agree that Byrn did not suppress or conceal.

Another "issue" which is not an issue is corroboration. Aronhime does not contend that Byrn failed to adequately corroborate its case-in-chief.

In large measure, the following findings have been taken from Appendix II of Byrn Reply 3 (Paper 75). Appendix II is a statement of material facts required by the rules and the STANDING ORDER. The statement of materials facts, which includes all facts proposed by both

parties, includes whether or not those facts are admitted by the opponent of the proponent of the finding. In some instances, we have modified the language of the proposed findings and we indicate when a proposed finding has been admitted by the opponent of the proponent of the finding. We also comment on why we decline to agree with a denial of finding. Any reader should understand that while our findings are based on the findings proposed by both parties, the findings are made after full review of the underlying record.

Byrn witnesses

At least the following witnesses testified in support of Byrn:

(1) Dr. Aeri Park (inventor);

(2) Petinka Vlahova (inventor);

(3) Brenton Russell (non-inventor);

(4) Ann McKenzie (non-inventor);

(5) Dr. Joseph Krzyzaniak (inventor);

(6) Lien Koztecki (non-inventor);

(7) Tracy Stone (non-inventor);

(8) Henry Morrison (inventor);

(9) Dr. Joseph Stowell (non-inventor);

(10) Don Hallenbeck; and

(11) Greg Thomas.

Aronhime elected not to cross-examine any of the witnesses called by Byrn.

Credibility finding

We find the testimony of the witnesses, and the documentary evidence relied upon by the witness, to be highly credible.

Research project at SSCI, Inc.

Dr. Park testified that at a time prior to the end of 1999, SSCI Inc., West Lafayette, Indiana, started a research collaboration with Parke-Davis/Warner-Lambert, Inc. (now part of Pfizer Inc.) involving the compound atorvastatin. Ex. 2088, ¶ 2. Admitted by Aronhime.

The experimental work discussed in Dr. Park's testimony which mentions "atorvastatin" or "crystalline atorvastatin" was done with atorvastatin calcium, as disclosed in the Byrn provisional application and Byrn's involved patent. Ex. 2088, ¶ 9. Admitted by Aronhime.

By the end of 1999, that research collaboration had begun to focus on identifying and characterizing new crystalline forms of atorvastatin (herein the "Project"). Ex. 2088, ¶ 2. Admitted by Aronhime.

The Project team members included:

(1) Dr. Stephen Byrn (named inventor),

(2) Dr. Aeri Park (named inventor),

(3) Henry Morrison (named inventor identified in the Byrn patent as Henry Grant Morrison II),

(4) Petinka Vlahova (named inventor),

(5) Karen Gushurst (named inventor identified in the Bryn patent as Karen Sue Gushurst), and

(6) David Coates (named inventor identified in the Byrn patent as David Andrew Coates). Ex. 2088, ¶ 2. Admitted by Aronhime.

Dr. Aeri Park was the Senior Research Investigator (project leader) of the Project. Ex. 2088, ¶ 2. Admitted by Aronhime.

During the progress of the Project, (1) Dr. Park's collaborators and coworkers shared all of their experimental results with her on a regular basis,

and (2) Dr. Park was provided with all experimental results as soon as the results were obtained. Ex. 2088, ¶ 8; Ex. 2089, ¶ 5. Admitted by Aronhime.

Diffractograms of new samples and other experimental results were reviewed and discussed at weekly meetings held in connection with the Project. Ex. 2088, ¶ 8; Ex. 2089, ¶ 4. Admitted by Aronhime.

Sample 299-61-04

In the time period 23-28 February 2000, Petinka Vlahova prepared a sample of crystalline atorvastatin identified as "299-61-04." Ex. 2088, ¶ 16; 2089, ¶ 6. Admitted by Aronhime.

Preparation of the sample of crystalline atorvastatin identified as "299-61-04" is recorded on pages 61 and 71 of SSCI notebook No. 299. Ex. 2088, ¶ 16; Ex. 2089, ¶ 6; Ex. 2028. Admitted by Aronhime. The Project identified at the top of page 61 is Atorvastatin Ca—PMS (PDWL).

Pages 61 and 71 of SSCI notebook No. 299 were witnessed by Brenton Russell on 29 February 2000. Mr. Russell was aware of the Project. Ex. 2088, ¶ 16; Ex. 2089, ¶ 6; Ex. 2028; Ex. 2093, ¶ 4. Admitted by Aronhime.

A diffractogram of sample "299-61-04" was prepared by Ann McKenzie on 01 March 2000 using a Shimadzu diffractometer. Ann McKenzie provided a copy of the diffractogram to Petinka Vlahova. Ex. 2088, ¶ 16; Ex. 2089, ¶ 6; Ex. 2029; Ex. 2090, ¶ 2. Admitted by Aronhime.

On or about 01 March 2000 but no later than the group's weekly meeting, Petinka Vlahova discussed the diffractogram pattern obtained from sample 299-61-04 with Dr. Park and other project coworkers. Ex. 2088, ¶ 16; Ex. 2089, ¶ 6. Admitted by Aronhime.

At that time, Dr. Park and Petinka Vlahova recognized that the peaks on the diffractogram taken from sample 299-61-04 (1) were different from the peaks on diffractograms of known crystalline atorvastatin forms and (2) might indicate a new crystalline form of atorvastatin. Ex. 2088, ¶ 16; 2089, ¶ 6. Denied by Aronhime. According to Aronhime, at the time indicated, Dr. Park and Petinka Vlahova did not understand the composition and structure of sample 299-61-04 and thus did not have a basis for believing that sample 299-61-04 might be a new crystalline form of atorvastatin. Aronhime misses the mark. All that Dr. Park and Petinka Vlahova recognized was the peaks were different any known crystalline atorvastatin form and that the difference might indicate a new crystalline form of atorvastatin.

Dr. Park has prepared a peak list, using conventional methodology whereby the raw data for a diffractogram pattern is converted to corresponding numerical values, from the diffractogram of sample "299-61-04." Ex. 2088, ¶ 17; Ex. 2030. Admitted by Aronhime.

All of the peaks recited in Byrn claim 6, ± 0.2 degrees two theta, and in Count 2 correspond to peaks which are present in the diffractogram taken from sample 299-61-04. Ex. 2088, ¶¶ 17-19. Admitted by Aronhime.

Dr. Park has compared the diffraction pattern of 299-61-04 prepared on 01 March 2000 (Ex. 2030) to the diffraction pattern of Form X shown as Figure 6 of the involved Byrn patent (2001, Figure 6). Ex. 2088, ¶ 20. Admitted by Aronhime.

Byrn claim 6 recites 2-theta values (peak positions) obtained using a Shimadzu diffractometer. Ex. 2088, ¶ 19. Admitted by Aronhime.

Both Dr. Park and Dr. Joseph Krzyzaniak observe a clear overall gross similarity between the two diffractograms, such that they have no

doubt that the sample prepared, characterized and recognized to be a novel crystalline form on or about 01 March 1, 2000 identified as 299-61-04 was a sample of what is called "Form X" crystalline atorvastatin in the '729 patent. Ex. 2088, ¶ 20; Ex. 2102, ¶ 7; Ex. 2103, Sheet 1. Denied by Aronhime.

According to Aronhime, since the diffractograms cannot indicate solvation or hydration states, Drs. Park and Krzyzaniak cannot have no doubt that the sample prepared on or about 01 March 1, 2000 has the same solvation or hydration state as the sample of what is called "Form X" crystalline atorvastatin in the Byrn patent. Aronhime reasons, therefore, that Dr. Park and Dr. Krzyzaniak cannot have no doubt that the sample prepared on or about March 1, 2000 is a sample of what is called "Form X" crystalline atorvastatin in the '729 patent.

The difficulty with Aronhime's denial is that Byrn claim 6 and therefore the Byrn alternative of Count 2 do not require a solvate or any degree of hydration. No mention whatsoever appears in the Byrn alternative of the count with respect to solvation. Likewise, not only does no degree of hydration appeal ("or hydrate thereof"), Byrn claim 6 does not require a hydrate—the compound is either (1) not a hydrate or (2) if it is a hydrate, no degree of hydration is specified. As noted earlier in this opinion, Aronhime has admitted that the compound prepared by Petinka Vlahova was a sample of crystalline atorvastatin identified as "299-61-04."

Dr. Park and Dr. Krzyzaniak support their opinion by reference to an overlay of the diffractogram of the sample to the diffractogram of Byrn Figure 6. Ex. 2088, ¶ 20; Ex. 2102, ¶¶ 2-7; Ex. 2103, Sheet 1. Denied by Aronhime. According to Aronhime, since the overlay is based on diffractograms, the overlay cannot provide information about solvation and hydration state and thus cannot support an opinion that the sample prepared

on or about March 1, 2000 is a sample of what is called "Form X" crystalline atorvastatin in the Byrn patent. For the reasons given in Dr. Krzyzaniak's testimony, we disagree with Aronhime.

Sample 299-61-04 is described in Dr. Park's 26 July 2000 report as the "First Form X obtained, used as a standard for XRPD pattern. comparison." Ex. 2088, ¶¶ 6 and 21; Ex. 2021, page 26, Table 13, third entry of section "IPA:H_2O 9:1" in fourth column, and associated footnote "c." Aronhime admits that sample 299-61-04 is so described in the report.

Samples 299-95-01 and 299-95-08

On 5-10 April 2000, Petinka Vlahova prepared samples of crystalline atorvastatin identified as "299-95-01" and"299-95-08" as shown on pages 95 and 97 of SSCI notebook No. 299. Ex. 2088, ¶ 22; Ex. 2089, ¶ 7; Ex. 2031. Admitted by Aronhime. The "Project" identified at the top of page 95 of SSCI notebook No. 299 is "Atorvastatin Ca—PMS." Ex. 2031. "Ca" obviously means "calcium."

Pages 95 and 97 of SSCI notebook No. 299 were witnessed by Brenton Russell on April 07 and April 14, 2000, respectively. Mr. Russell was aware of the Project. Ex. 2088, ¶ 22; Ex. 2089, ¶ 7; Ex. 2093, ¶¶ 3, 4 and 6. Admitted by Aronhime.

Diffractograms of those samples were prepared by Lien Koztecki on April 13, 2000 and the diffractograms were provided to Petinka Vlahova. Ex. 2088, ¶ 22; Ex. 2089, ¶ 7; Ex. 2027 [testimony of Koztecki], ¶ 2; Ex. 2022 [diffractogram of 299-95-01]; Ex. 2032 diffractogram of 299-05-08]. Admitted by Aronhime.

On or about 13 April 2000, Dr. Park (1) discussed these diffractograms [Ex. 2022 and Ex. 2032] with Petinka Vlahova and (2) noted

their similarity to the diffractogram taken from sample 299-61-04. Ex. 2088, ¶ 22; Ex. 2089, ¶ 7. Admitted by Aronhime.

Dr. Park prepared peak lists from the diffractograms of samples 299-95-01 and 299-95-08. Ex. 2088, ¶ 23; Ex. 2023; Ex. 2033. Admitted by Aronhime.

All of the peaks recited in Byrn claim 6, ± 0.2 degrees two theta, and in Count 2 correspond to peaks found in the diffractograms prepared from samples 299-95-01 and 299-95-08 and the peak lists prepared from those diffractograms. Ex. 2088, ¶ 24. Admitted by Aronhime.

Dr. Park and Dr. Krzyzaniak have compared the diffraction patterns of samples 299-95-01 (Ex. 2022) and 299-95-08 (Ex. 2032) to the diffraction pattern of Form X shown as Figure 6 of the Byrn patent (2001, Figure 6), and both Dr. Park and Dr. Krzyzaniak observe a clear overall gross similarity between the two diffractograms. Ex. 2088, ¶ 25; Ex. 2102, ¶ 7. Aronhime admits that Dr. Park and Dr. Krzyzaniak so testified.

Dr. Park and Dr. Krzyzaniak support an opinion that the diffractograms of samples 299-95-01 and 299-05-08 are essentially the same as the diffractogram of Fig. 6 of the Byrn patent reference to an overlay of the diffractograms of these samples to the diffractogram of Byrn Figure 6. Ex. 2088, ¶ 25; Ex. 2102, ¶¶ 2-7, Ex. 2103, Sheets 2 and 3. Denied by Aronhime. According to Aronhime, since the overlay is based on diffractograms, it cannot provide information about solvation and hydration state and thus cannot support such an opinion. As noted earlier, solvation is not required by the count and the degree of hydration if any is not a requirement of Count 2.

Samples 299-95-01 and 299-95-08 are identified as being "Form X" in a 26 July 2000 report. Ex. 2021, page 26, table; Ex. 2088, ¶ 26. Admitted by Aronhime.

Sample 323-50-01

On 13-18 April 2000, Petinka Vlahova prepared a sample of crystalline atorvastatin identified as "323-50-01" as shown on pages 50, 51 and 55 of SSCI notebook No. 323. Ex. 2088, ¶ 28; Ex. 2089, ¶ 8; Ex. 2034. Admitted by Aronhime. The Project identified at the top of pages 50, 51 and 55 of notebook No. 323 is "Atorvastatin Ca—PNS (PDWL). On page 55, there is a statement that "[t]he same [was] submitted for XRPD."

A diffractogram of sample 323-50-01 was (1) prepared by Tracy Stone on 18 April 2000 and (2) provided to Petinka Vlahova. Ex. 2088, ¶ 28; Ex. 2089, ¶ 8; Ex. 2035 [diffractogram of 323-50-01]; Ex. 2104, ¶ 2. Admitted by Aronhime.

On or about 18 April 2000, Dr. Park discussed the diffractogram with Petinka Vlahova and they recognized its similarity to the diffractograms previously taken from samples (a) 299-95-01, (b) 299-95-08 and (c) 299-61-04. 2088, ¶ 28; 2089, ¶ 8. Admitted by Aronhime.

Between 19 April and 03 May 2000, Petinka Vlahova investigated the stability of sample 323-50-01 in a humid atmosphere, using an aliquot of that sample, and referred to the sample as "Form X" in that entry. Ex. 2088, ¶ 33; Ex. 2089, ¶ 10; Ex. 2095. Admitted by Aronhime.

The sample stored in humid conditions (the aliquot of sample 323-50-01 designated as 323-58-01) was analyzed by XRPD by Ann McKenzie and found to show a Form X powder pattern, showing stability of Form X at 95% relative humidity over two weeks. Ex. 2088, ¶ 33; Ex. 2089, ¶ 10; Ex. 2059; Ex. 2090, ¶ 3. Admitted by Aronhime.

Dr. Park prepared a peak list from the diffractogram of sample 323-50-01. Ex. 2088, ¶ 29; Ex. 2036. Admitted by Aronhime.

All of the peaks recited in Byrn claim 6, ± 0.2 degrees two theta, correspond to peaks found in the diffractogram prepared from sample 323-50-01 and the peak list prepared from that diffractogram. Ex. 2088, ¶¶ 30-31. Admitted by Aronhime.

Dr. Park and Dr. Krzyzaniak have compared the diffraction pattern of 323-50-01 prepared on 18 April 2000 (Ex. 2032) to the diffraction pattern of Form X shown as Figure 6 of the '729 patent (Ex. 2001, Figure 6), and both observe that the diffractograms are identical. Ex. 2088, ¶ 31; Ex. 2102, ¶ 7. Aronhime admits that Dr. Park and Dr. Krzyzaniak so testified.

Dr. Park and Dr. Krzyzaniak support their opinions by reference to an overlay of the diffractogram of the sample to the diffractogram of Byrn Figure 6. Ex. 2088, ¶ 31; Ex. 2102, ¶¶ 6-7, Ex. 2103, Sheet 4. Admitted by Aronhime.

Sample 323-50-01 is identified as Form X in the 26 July 2000 report. Ex. 2088, ¶ 32; Ex. 2021, page 27, Table 14. Admitted by Aronhime.

The diffractogram taken from sample 323-50-01 is the same as the diffractogram shown as Figure 6 in the Byrn patent. Ex. 2088, ¶ 31; Ex. 2089, ¶ 8. Admitted by Aronhime.

Sample 323-51-01

On 14-18 April 2000, Petinka Vlahova prepared a sample of crystalline atorvastatin identified as "323-51-01" as shown on pages 51 and 55 of SSCI notebook No. 323. Ex. 2088, ¶ 34; Ex. 2089, ¶ 9; Ex. 2034. Admitted by Aronhime. The Project identified at the top of page 51 of notebook No. 323 is "Atorvastatin Ca—PMS (WLPD)."

A diffractogram of sample 323-51-01 was prepared by Tracy Stone on 18 April 2000, which was provided to Petinka Vlahova. Ex. 2088, ¶ 34; Ex. 2089, ¶ 9; Ex. 2104, ¶ 3; Ex. 2038. Admitted by Aronhime.

On or about 18 April 2000, Dr. Park discussed the diffractogram of sample 323-51-01 with Petinka Vlahova and it was recognized that sample 323-50-01 was Form X crystalline atorvastatin. Ex. 2088, ¶ 34; Ex. 2089, ¶ 9. Denied by Aronhime. According to Aronhime, since diffractograms cannot indicate solvation or hydration state, it cannot have been recognized that sample 323-50-01 was Form X crystalline atorvastatin. We have already indicated why we believe the basis for Aronhime's denial is not consistent with the language of Byrn claim 6 or the Byrn alternative of Count 2.

Dr. Park prepared a peak list from the diffractogram of sample 323-51-01. Ex. 2088, ¶ 34; Ex. 2039. Admitted by Aronhime.

All of the peaks recited in Byrn claim 6, ± 0.2 degrees two theta, and in Count 2 correspond to peaks found in the diffractogram prepared from sample 323-51-01 and the peak list prepared from that diffractogram. Ex. 2088, ¶ 35. Admitted by Aronhime.

Dr. Park and Dr. Krzyzaniak have compared the diffraction pattern of sample 323-51-01 prepared on 18 April 2000 (Ex. 2038) to the diffraction pattern of Form X shown as Figure 6 of the Byrn patent (Ex. 2001, Figure 6), and both observe a clear overall gross similarity between the two diffractograms, to conclude that the sample was "Form X" crystalline atorvastatin within the meaning of the Byrn patent. Ex. 2088, ¶ 35; Ex. 2102, ¶ 7; Ex. 2103, Sheet 5. Denied by Aronhime. According to Aronhime, since diffractograms cannot indicate solvation or hydration state, it cannot have been recognized that sample 323-50-01 was Form X

crystalline atorvastatin within the meaning of the '729 patent. We have previously stated why solvation and hydration state is not applicable to Byrn claim 6 and the Byrn alternative of Count 2.

Dr. Park and Dr. Krzyzaniak support their opinion by reference to an overlay of the diffractogram of the sample to the diffractogram of Byrn Figure 6. Ex. 2088, ¶ 35; Ex. 2102, ¶ 7; Ex. 2103, Sheet 5. Denied by Aronhime. According to Aronhime, such an overlay, since it is based on diffractograms, cannot provide information about the solvation or hydration state and therefore cannot support such an opinion. We have already discussed our basis for disagreeing with Aronhime's denial.

Sample 323-51-01 is identified as Form X in Dr. Park's 26 July 2000 report. Ex. 2088, ¶ 36; Ex. 2021, page 27, Table 14 and footnote "e". Admitted by Aronhime.

Sample 323-64-03

On 21-28 April 2000, Petinka Vlahova prepared a sample of crystalline atorvastatin identified as "323-64-03" as shown on pages 64 and 78 of SSCI notebook No. 323. Ex. 2088, ¶ 37; Ex. 2089, ¶ 11; Ex. 2040. Admitted by Aronhime. The Project identified at the top of page 64 of notebook No. 323 is "Atorvastatin CA—PMS (PDWL). In describing the experiments, the author of the notebook pages explicitly mentions the use of "Atorvastatin Ca—PMS".

A diffractogram of sample 323-64-03 was prepared on 28 April 2000. Ex. 2088, ¶ 37; Ex. 2089, ¶ 11; Ex. 2041. Admitted by Aronhime.

Dr. Park prepared a peak list from the diffractogram of sample 323-64-03. Ex. 2088, ¶ 37; Ex. 2042. Admitted by Aronhime.

All of the peaks recited in Byrn claim 6, ± 0.2 degrees two theta, and in Count 2 correspond to peaks found in the diffractogram prepared from

sample 323-64-03 and the peak list prepared from that diffractogram. Ex. 2088, ¶ 38. Admitted by Aronhime.

Based on the overlay of the diffractogram from sample 323-64-03 (Ex. 2038) to the diffraction pattern of Form X shown as Figure 6 of the Byrn patent (Ex. 2001, Figure 6), Dr. Park and Dr. Krzyzaniak conclude that the sample was "Form X" crystalline atorvastatin. Ex. 2088, ¶ 38; Ex. 2102, ¶ 7; Ex. 2103, sheet 6. Denied by Aronhime. According to Aronhime, such an overlay, since it is based on diffractograms, cannot provide information about the solvation or hydration state and thus cannot support such an opinion. We have already expressed the basis for our disagreement with Aronhime's denial.

Sample 323-64-03 is identified as Form X in Dr. Park's 26 July 2000 report. Ex. 2088, ¶ 39; Ex. 2021, page 29, Table 16. Admitted by Aronhime.

Knowledge of the art

It is well known in the art of crystallography and organic solid state chemistry that crystalline forms of organic molecular crystals (which include pharmaceutical compounds) can exist in various states of solvation or hydration and show equivalent XRPD powder patterns. Ex. 2105, ¶ 20. Admitted by Aronhime.

Samples 436-77-01

On 10-16 October 2000, Henry Morrison prepared a sample of Form X crystalline atorvastatin identified as "436-77-01" as shown on pages 77, 79 and 88 of SSCI notebook No. 436. Ex. 2088, ¶ 41; Ex. 2046. Admitted by Aronhime.

A diffractogram of sample 436-77-01 was made by Ann McKenzie prior to 09 November 2000. The diffractogram was provided to Henry

Morrison. Ex. 2090, ¶ 4; Ex. 2107; Ex. 2113, ¶ 2. While Byrn proposed finding 72 was admitted by Aronhime, in its rebuttal evidence Byrn advised Aronhime and the Board that the diffractogram mentioned in proposed finding 72 (Ex. 2047) is not correctly identified. The diffractogram of Ex. 2107 was analyzed by Dr. Park on 18 October 2000. The diffractogram of Ex. 2047 was analyzed by Dr. Park on 09 November 2000. Ex. 2113, ¶¶ 2-4.

Dr. Park prepared a peak list from the diffractogram of sample 436-77-01. Ex. 2088, ¶ 41; Ex. 2048. Admitted by Aronhime.

The peak list and the overlay of the diffractogram from sample 436-77-01 to Figure 6 confirm that sample 436-77-01 was Form X crystalline atorvastatin. Ex. 2088, ¶ 41; Ex. 2102, ¶ 7; Ex. 2103, sheet 7. Denied by Aronhime. According to Aronhime, such a peak list and overlay, since they are based on diffractograms, cannot provide information about solvation or hydration state and thus cannot support such a confirmation.

Dr. Joseph Stowell

From 1999 to present, Joseph Stowell, PhD, was "Study Director" in connection with the Project. Ex. 2026, ¶ 3. Admitted by Aronhime.

In his capacity as Study Director, Dr. Stowell was asked to review the experimental results and the conclusions being drawn, as compiled in the form of a report, and to provide his opinion to SSCI on the scientific integrity and validity of the reported results and conclusions. Ex. 2026, ¶ 4. Admitted by Aronhime.

In 2000, Dr. Stowell was requested specifically to review the SSCI report dated 26 July 2000 titled "Polymorph Screen of Atorvastatin." Ex. 2026, ¶ 5. Admitted by Aronhime.

Dr. Stowell had finished his review, and signed the 26 July 2000 report, by 27 July 2000, the date of his signature on the report. Ex. 2026, ¶ 5; Ex. 2021, cover page. Admitted by Aronhime.

Dr. Stowell testified that it is his current opinion, which was also his opinion at the time of the report, that the report establishes to his satisfaction that the production and identification of an atorvastatin crystalline form identified in the report as "Form X." From the report, it was clear to Dr. Stowell that Form X had been actually produced, and had been recognized to be a new crystalline form of atorvastatin. Ex. 2026, ¶ 6. Aronhime admits that Dr. Stowell so testified.

From the evidence provided in the 26 July 2000 report, the Form X crystalline atorvastatin described therein could be recognized as a single, stable, and reproducible form of crystalline atorvastatin. Ex. 2026, ¶ 7. Admitted by Aronhime.

Dr. Stowell confirms that "Form X" as described in the 26 July 2000 report is the same "Form X" which is described in the Byrn patent. Ex. 2026, ¶ 8. Denied by Aronhime. According to Aronhime, since there is no indication in the report of the solvation or hydration state of the form described therein, the form described in the report cannot be "confirmed" to be the same "Form X" which is described in the Byrn patent. We have already expressed why we disagree with Aronhime's denial.

Form X is a new form of a familiar pharmaceutical compound. Ex. 2088, ¶ 66; Ex. 2026, ¶ 9. Admitted by Aronhime.

At the time Dr. Stowell reviewed the report disclosing crystalline Form X in July, 2000, it was apparent that Form X would have the same pharmacological mode of activity as amorphous atorvastatin and previous

crystalline forms of atorvastatin, albeit not necessarily at the same rate of activity. Ex. 2026, ¶ 9; Ex. 2088, ¶ 66. Admitted by Aronhime.

Other properties of Form X

The 26 July 2000 report states that: "Characterization studies of all of the new forms are in progress and will be reported at a later time." Ex. 2088, ¶ 49; Ex. 2021, p. 9, last sentence under "Conclusion." Admitted by Aronhime.

Subsequent to the 26 July 2000 report, Dr. Byrn and Dr. Park, in collaboration with other Project members, discussed further experiments to characterize Form X crystalline atorvastatin and prepared a protocol dated 31 July 2000. Ex. 2088, ¶ 50-51; Ex. 2060; Ex. 2061. Admitted by Aronhime.

The experimental work outlined in the protocol was carried out at SSCI starting in August 2000. Ex. 2088, ¶ 51. Aronhime cannot admit or deny.

Experimental results obtained for Form X subsequent to the 26 July 2000 report were included in the provisional patent application, including: (1) characterization of Form X by solid state NMR, (2) characterization of Form X by Raman spectroscopy, (3) water content of Form X as determined by Karl Fisher analysis, and (4) melting point determined by differential scanning calorimetry (DSC). Ex. 2088, ¶ 53. Aronhime admits that such characterization appears in the provisional patent application.

Those results are shown in the Byrn provisional patent application. Ex. 2088, ¶ 53; Ex. 2064, pages 16-17 (ssNMR data), pages 17-18 (Raman spectroscopy data), page 45, line 22 (water content data), and page 45:21 (melting point). Admitted by Aronhime.

The ssNMR analysis of Form X which is provided in the provisional patent application was carried out at SSCI by Don Hallenbeck on 24 October 2000, using sample 436-77-01 prepared by Henry Morrison on 10 October 2000. Ex. 2088, ¶ 54; Ex. 2097, Ex. 2098, ¶¶ 3-4; Ex. 2091. Admitted by Aronhime.

The results of the ssNMR analysis of Form X done on 24 October 2000 (Ex. 2091) appear as Figure 13 in the provisional application (Ex. 2064) and Figure 29 in the Byrn patent (Ex. 2001). Ex. 2088, ¶ 54; Ex. 2064, Fig. 13; Ex. 2001, Fig. 29. Admitted by Aronhime.

Raman spectroscopy of Form X—also made from an analysis of sample 436-77-01—was performed at SSCI by Greg Thomas on 23 October 2000. Ex. 2088, ¶ 55; Ex. 2099, ¶¶ 3-7; Ex. 2100. Admitted by Aronhime.

The results of the Raman spectroscopic analysis of Form X done on 23 October 2000 appear as Figure 18 of the provisional application (Ex. 2064) and Figure 34 in the Byrn patent (Ex. 2001). Ex. 2088, ¶ 55; Ex. 2064, Fig. 18; Ex. 2001, Fig. 34. Admitted by Aronhime.

On 06 December 2000, Dr. Park sent samples of Form X (465-35-05, 465-35-06, 465-35-07, and 465-35-08) to Tim Hurley at Parke-Davis/Warner-Lambert, for analysis of chemical stability (40 °C at 75% relative humidity, and 80 °C, each for two and four weeks). Ex. 2088, ¶ 57; Ex. 2024. Admitted by Aronhime.

Stability of the new crystalline forms is described in the provisional application (page 3:24) and the Byrn patent (col. 2:39). Ex. 2064, page 3:24 Ex. 2001, col. 2:39. Admitted by Aronhime.

Aronhime's opposition

According to Aronhime, Byrn has not shown that prior to Aronhime's earliest construction reduction to practice that Byrn had a definite idea that

the crystal structure of Form X atorvastatin contains three (3) molecules of water per molecule of atorvastatin. Admitted by Byrn.

Byrn did not defined Form X has a trihydrate. We do not accept Aronhime proposed finding 142: "Byrn has defined Form X as a trihydrate." The Byrn specification states that Form X has about 3 mol water per mole atorvastatin and Byrn claim 6 claims a "hydrate" not a "tri-hydrate." Dr. Robin D. Rogers, an expert witness called by Aronhime, testified that the Byrn patent states that Form X is a trihydrate. Ex. 1078, ¶ 7. We can agree with Dr. Rogers to the extent that Form X *may* be a trihydrate; we cannot agree that it *must* be a trihydrate.

The Byrn patent does not state that each of Methods A, B, and C produces a trihydrate. We do not accept Aronhime's proposed finding 144. The statement in the Byrn patent that a measurement by Karl Fischer that Methods A, B, and C result in 3.5% means that the total water (bound and not bound in the crystal) is 3.5% and not that the crystal is a trihydrate. Dr. Rogers testified that one of ordinary skill in the art would view "these disclosures" (taken to mean the information set out in Aronhime proposed finding 144) in the Byrn patent as defining Form X has a trihydrate. We decline to credit Dr. Rogers' testimony because the Byrn patent says that Form X has *about* 3 mol of water per mol of atorvastatin. Dr. Rogers' post-litigation testimony is not consistent with Byrn's pre-litigation disclosure.

According to Aronhime, Form X is a solvate of atorvastatin. Aronhime proposed finding 148.

A person having ordinary skill in the art would understand that a powder X-ray diffractogram (PXRD) does not provide information

regarding the presence or absence of solvent in a crystal. Ex. 1078, ¶ 12. Admitted by Byrn.

According to Aronhime, an X-ray powder diffractogram (PXRD) does not show conception of the invention defined by the count because a PXRD does not, and indeed cannot, be used to identify whether a crystalline form is a solvate such as a hydrate. Aronhime proposed finding 175; Ex. 1078, ¶¶ 10-14. Byrn denies this proposed finding. Byrn properly denies the proposed finding since it relates to a question of law—whether certain evidence shows conception.

There is no Byrn inventor testimony that, prior to Aronhime's earliest constructive reduction to practice, the Byrn inventors understood that Form X was a solvate or hydrate of atorvastatin based on the PXRD spectrum or any other evidence. Ex. 1078, ¶ 17. Admitted by Byrn.

Byrn rebuttal facts

The Byrn specification does not restrict Form X to a crystalline form of atorvastatin having a particular solvate or water content. Byrn proposed finding 188; Ex. 2116, ¶ 5.

Dr. Rogers testified as follows [matter in brackets added]:

> Both visual comparisons of Exhibits 1018-1020 [diffractograms of atorvastatin made by Aronhime in reproducing Methods A, B, and C] and Figure 6 of Exhibit 1017 [the Byrn patent] (column 29, lines 39-42) show that all of the peaks reported by Byrn for Form X, are present in the three spectra in Exhibits 1018-1020 and that there are no unaccounted for peaks of any significant intensity.

See also Byrn proposed finding 194.

F. Discussion—admissibility of evidence and priority

Admissibility of Byrn Ex. 2116 and Byrn Ex. 2117

Aronhime objects to the admissibility of Ex. 2116 and Byrn Ex. 2117. Aronhime motion 7 (Paper 77).

According to Aronhime, the exhibits constitute improper rebuttal testimony.

Ex. 2116 is rebuttal testimony of Dr. Park.

Ex. 2117 is Morris, Structural Aspects of Hydrates and Solvates, which is said to be Chapter 4 in H.G. Brittain, "Polymorphism in Pharmaceutical Solids, pages 145-153 (no date).

Byrn maintains, in opposing Aronhime motion 7 that the evidence simply responds to arguments made in Aronhime opposition 3 (Paper 74). See Byrn opposition 7 (Paper 81).

Our findings reveal the extent to which we have relied on Dr. Park's rebuttal testimony. Basically, she called to our attention an error in her direct testimony indicating that her direct testimony she made an incorrect reference to a diffractogram. We see nothing wrong in Byrn having called the error to our attention when it did so.

We have not found it necessary to consider, discuss or otherwise rely on Ex. 2117, which we will note is not dated.

Disposition of Aronhime motion 7

Upon consideration of Aronhime motion 7, the motion is (1) denied to the extent that it seeks to exclude those portions of Ex. 2116 mentioned in our findings and (2) is otherwise dismissed as moot.

General observations about priority

We start with a couple of observations about priority cases.

First, no priority case is perfect. If it were, the opponent would concede priority and that would end the matter.

Second, in presenting a priority case, a party tells us a "story" about events which occurred in the past. Our basic function is to determine whether the "story" is sufficient and credible. In other words, is the relevant evidence sufficient to establish that a party has told a "credible story" to justify holding that the party has a date of invention prior to its opponent's date of invention—in this case Aronhime's earliest constructive reduction to practice. For reasons which follow, we think that Byrn has presented a credible story and accordingly hold that Byrn actually reduced to practice the invention defined by Count 2 prior to Aronhime's earliest constructive reduction to practice.

Byrn's case-in-chief

The principal problem in this case, at least from Aronhime's point of view, is the scope of Count 2. Count 2 is made up of an Aronhime portion and a Byrn portion. Aronhime has issues with the scope and meaning of the Byrn portion of Count 2—which is essentially Byrn claim 6. We do not share Aronhime's concerns.

As indicated early in this opinion, the Byrn portion of Count 2 covers "Form X atorvastatin" or "a hydrate thereof" having certain peaks set out in the count.

Based on our evaluation of the evidence, applying our best judgment to the facts, we find and hold that Byrn made numerous embodiments of "Form X atorvastatin or a hydrate thereof" having the peaks set out in Count 2 prior to Aronhime's earliest constructive reduction to practice.

A composition of matter is reduced to practice when (1) it is completely composed, *Corona Cord Tire Co. v. Dovan Chem. Corp.*,

276 U.S. 358, 383 (1928); quoted in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 57 n.2 (1998), and (2) its utility is established *Brenner v. Manson*, 383 U.S. 519 (1966).

In the case of a composition of matter which is a new crystalline form of an otherwise old composition of matter, the inventor must recognize or appreciate the existence of the new form. *Silvestri v. Grant*, 496 F.2d 593, 597, 181 USPQ 706, 708 (CCPA 1974).

Evans v. Eaton, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000) makes the following observations:

> In an interference proceeding, a party seeking to establish an actual reduction to practice of a product ... must satisfy a two-prong test: (1) the party constructed an embodiment [, i.e., made the composition of the count,]... that met every element of the interference count and (2) the embodiment ... operated for its intended purpose.
>
> ***
>
> With regard to the first prong, this Court's well-established precedent requires that the ... performed process include the precise elements recited in the count.

It seems clear to us that Byrn has met its burden under *Corona*, *Manson*, *Evans v. Eaton* and *Silvestri v. Grant*. (1) The products made by Vlahova (and on some occasions, others), (2) analyzed for X-ray powder diffraction by McKenzie (and on some occasions, others), (3) the recognition by Dr. Park (and others) based on the diffractograms that a new crystalline form had been developed, (4) the numerous confirmations of the new form through repeated making and analyzing of other embodiments of

Form X atorvastatin, (5) the confidence shown to include the results in a July 2000 report to company management, (6) Dr. Stowell's (a company management official) signing of the report, (7) the consistency between the testimony and the documentary evidence, (8) the reasonably contemporaneous witnessing of inventor notebooks, and (9) the overlay evidence developed by Dr. Park and Dr. Krzyzaniak, collectively and credible show that prior to Aronhime Byrn made and appreciated an embodiment within the scope of the Byrn portion of Count 2. As previously noted, testing for utility is not an issue in this case.

In finding that the Byrn case-in-chief is more than sufficient, we have not relied upon events which transpired after Aronhime's earliest construction reduction to practice or events which are said to have occurred in connection with sending samples to Galbraith Laboratories.

Aronhime's views

A first attack by Aronhime on Byrn's "story" is that Byrn forgot to prove that the various embodiments made by Vlahova were "trihydrates." *See, e.g.*, Aronhime opposition 3, page 3. According to Aronhime, "Form X atorvastatin" has to be a trihydrate, *i.e.*, three mol of water per mol of atorvastatin—no more no less. We cannot agree. Count 2 calls for "Form X atorvastatin or a hydrate thereof. It does not call for a trihydrate and therefore Byrn was under no obligation to prove that Vlahova (and on occasions, others) made a trihydrate. Given the language of Count 2, all Byrn had to show was that (1) Form X atorvastatin or (2) a hydrate of Form X atorvastatin was made which when analyzed by X-ray powder diffraction as set out in the count results in the peaks set out in the count. All the embodiments made by Vlahova (on some occasions, others) had those peaks.

A second attack by Aronhime on Byrn's "story" is that "Form X" is a solvate and Byrn also forgot to prove that the various embodiments made by Vlahova (and on some occasions, others), were solvates and, if solvates, the nature of the solvates. *See, e.g.*, Aronhime opposition 3, page 4. Presumably Aronhime feels that the embodiments relied upon by Byrn are solvates of isopropanol since that was the solvent used to make the embodiments relied upon—as well as those described in the Byrn specification. The Byrn portion of Count 2 does not call for a solvate. Accordingly, it is not clear why Aronhime insists that Byrn had to prove that the Form X atorvastatin embodiments upon which Byrn relies were solvates. Whether or not the various embodiments relied upon were or were not solvates, those embodiments fall within the scope of the Byrn portion of Count 2.

Reliable testimony offered by Aronhime shows that the diffractograms generated by McKenzie (and on some occasions, others) would not permit one skilled in the art to determine whether the embodiments relied upon are or are not solvates. Dr. Rogers, Aronhime's witness, tells us that a person having ordinary skill in the art would understand that a powder X-ray diffractogram (PXRD) does not provide information regarding the presence or absence of solvent in a crystal. Ex. 1078, ¶ 12; *see also* Aronhime opposition 3, page 5: "[o]ne of skill in the art would understand that a powder X-ray diffractogram (PRRD) does not provide information regarding the presence or absence of solvent in the crystal."

What all this means is that whether or not the embodiments relied upon by Byrn are solvates, those embodiments fall within the scope of the count. Byrn does not have to prove something not required by the count. If

Aronhime felt that the count was too broad in that it did not explicitly include a "solvate" requirement, the proper course of action would have been to move to substitute a narrower count—one requiring that the Form X atorvastatin be in the form of a solvate—or for that matter a trihydrate.

It is apparent that Aronhime and Byrn have a disagreement on the scope of the Byrn portion of Count 2. For all the reasons given above, we agree with Byrn's construction of the Byrn portion of Count 2. There is a lot of discussion in the Aronhime opposition about the supposed significance of the way in which the Aronhime portion of Count 2 should be interpreted and why that should somehow be relevant to how the Byrn portion of Count 2 should be interpreted.

We do not agree that the construction of the Aronhime portion has anything to do with the construction of the Byrn portion. Why do we believe so? We have a rule that says that a claim in an interference is given its broadest reasonable construction *in light of the specification of the* application or *patent* in which it appears. 37 C.F.R. § 41.200(b) (2006). The Byrn portion of Count 2 comes from the Byrn specification, not the Aronhime specification. It is not apparent why we or Aronhime or Byrn would or should look to the Aronhime specification to interpret what the language in Byrn claim 6 or the Byrn alternative of Count 2 means.

To complete the analysis, we will note that the fact that there is an interference-in-fact does not mean that the Aronhime specification is used to construe the Byrn claim. All an interference-in-fact means is that the subject matter of the Byrn claim (not the language of the claims) defines the same patentable invention, *i.e.*, the subject matter of Byrn claim 6 anticipates or renders obvious the subject matter of involved Aronhime claims and vice-

versa. The meaning of each of the party's claims is determined by reference to the specification of that party.

Aronhime faults Byrn for not knowing every detail of the Form X atorvastatin embodiments made prior to the earliest Aronhime constructive reduction to practice. Aronhime seems to be insisting that Byrn had to know every detail of its relied upon embodiment in order to meet requirements said to be present in (1) *Board of Trustees of Florida State University v. American Bioscience*, 333 F.3d 1330, 1340, 67 USPQ2d 1252, 1259 (Fed. Cir. 2003), (2) *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) and (3) *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466, 1473, 43 USPQ2d 1935, 1941 (Fed. Cir. 1997). Suffice it to say that each of these three cases is distinguishable on its facts. Here, Byrn knew it had a Form X atorvastatin or a hydrate thereof having necessary diffractogram peaks. Nothing more was needed. More to the point is *Silvestri v. Grant* where the CCPA points out that what an inventor of a new crystalline form of an otherwise known compound needs to know is that it has a new form. Dr. Park certainly knew she had a new form and we are not going to require Dr. Park to know more than *Silvestri v. Grant* would require her to know.

G. Order

Upon consideration of Byrn motion 3, Aronhime combined motions 2-5 and Aronhime motion 7, and for the reasons given, it is

ORDERED that Byrn motion 3 is granted.

FURTHER ORDERED that Aronhime combined motions 2-5 are denied.

FURTHER ORDERED Aronhime motion 7 is denied to the extent that it seeks to exclude from evidence those portions of Byrn Ex. 2116 which form the basis for a few of our findings and is otherwise dismissed as moot.

FURTHER ORDERED that a judgment is entered in a separate paper concurrently herewith.

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Senior Administrative Patent Judge	
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